

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application.

LISTING OF CLAIMS:

1-37(cancelled).

38(currently amended). A multi-component pharmaceutical dosage form which comprises a plurality of sub-units, each sub-unit being selected from: a linker, a closure cap, a drug substance-containing capsule compartment which is soluble or disintegrable in a patient's gastro-intestinal environment for release of the drug substance contained in the capsule compartment, and a solid matrix comprising a polymer and containing a drug substance, the polymer being soluble, dispersible or disintegrable in a patient's gastro-intestinal environment for release of the drug substance contained in the solid matrix, in which said dosage form comprises at least two drug substance-containing sub-units, in which the sub-units are disposed in end-to-end relationship along a line, and have outer walls surrounding said line, in which at least one said sub-unit is joined to at least one other sub-unit by a joint comprising a plug constituting a unitary part of one of the joined units and a socket formed as a unitary part in the other of the joined sub-units, in which each of said plug and socket is radially smaller than the sub-unit of which it is a unitary part, and in which said plug closely fits into said socket, and said joined sub-units are secured together independently by a weld at the joint thereof and that the drug substance present in at least one sub-unit differs from the drug substance present in at least one other sub-unit.

39(previously presented). A multi-component pharmaceutical dosage form according to Claim 38 wherein the sub-units comprise a plurality of drug substance-containing capsule compartments adjacent to one another and welded together, each of said adjacent capsule compartments being soluble or disintegrable in a patient's gastro-intestinal environment, the drug substances contained in each of said adjacent capsule compartments being physically separated from the drug substance contained in at least one adjacent, drug substance-containing, capsule compartment by a wall made of a pharmaceutically acceptable polymer material.

40(previously presented). A multi-component pharmaceutical dosage form according to claim 38 in which at least one of the sub-units is a solid matrix comprising a polymer and containing a drug substance, the polymer being soluble, dispersible or disintegrable in a patient's gastro-intestinal environment.

41(previously presented). A multi-component pharmaceutical dosage form according to claim 38 in which at least one of the sub-units is a solid matrix comprising a polymer and containing a drug substance, the polymer being soluble, dispersible or disintegrable in a patient's gastro-intestinal environment, and at least one of the other sub-units is a drug substance-containing capsule compartment which is soluble or disintegrable in a patient's gastro-intestinal environment.

42(previously presented). A multi-component pharmaceutical dosage form according to claim 38 in which the sub-units are held together in an assembled dosage form by one or more welds from the group consisting of thermal welds, inductive welds and ultrasonic welds.

43(previously presented). A multi-component pharmaceutical dosage form according to claim 38 in which at least two adjacent sub-units are connected together by one or more ultrasonic welds.

44(previously presented). A multi-component pharmaceutical dosage form according to claim 38 in which two adjacent sub-units are connected by a linker unit and in which at least one of said two adjacent sub-units is connected to the linker unit by one or more ultrasonic welds.

45(previously presented). A multi-component pharmaceutical dosage form according to claim 38 in which each of two adjacent sub-units is a drug substance-containing capsule compartment which is soluble or disintegrable in a patient's gastro-intestinal environment, in which said adjacent sub-units are connected by a linker unit and in which at least one of said two adjacent sub-units is connected to the linker unit by one or more ultrasonic welds.

46(previously presented). A multi-component pharmaceutical dosage form according to claim 38 in which each of two adjacent sub-units is a drug substance-containing capsule compartment which is soluble or disintegrable in a patient's gastro-intestinal environment, in which said adjacent sub-units are connected by a linker unit, in which at least one of said two adjacent sub-units is connected to the linker unit by one or more ultrasonic welds, and in which the wall thickness of said at least one of said adjacent sub-units is in the range of about 0.3 to 0.5 mm.

47 (previously presented). A multi-component pharmaceutical dosage form according to claim 38 in which each of two adjacent sub-units is a drug substance-containing capsule compartment which is soluble or disintegrable in a patient's gastro-intestinal environment, in which said adjacent sub-units are connected by a linker unit, in which at least one of said two adjacent sub-units is connected to the linker unit by one or more ultrasonic welds, and in which said at least one of said two adjacent sub-units has a frusto-conical side wall gently tapering toward an end wall, the end wall having a flattened central portion and rounded edge connecting the flattened central portion to the frusto-conical side wall.

48(previously presented). A multi-component pharmaceutical dosage form

according to claim 38 in which each of two adjacent sub-unit is a drug substance-containing capsule compartment which is soluble or disintegrable in a patient's gastro-intestinal environment, in which said adjacent sub-units are connected by a linker unit, in which at least one of said two adjacent sub-units is connected to the linker unit by one or more ultrasonic welds, and in which said at least one of said two adjacent sub-units has a side wall and an end wall, the end wall having a flattened central portion and rounded edge connecting the flattened central portion to the side wall, the flattened central portion having a substantially planar outer surface over at least 5% of the outer surface area of the end wall.

49(previously presented). A multi-component pharmaceutical dosage form according to claim 38 in which two adjacent sub-units are connected by a linker unit, in which at least one of the two adjacent sub-units is connected to the linker unit by a connection comprising interlocking tenons and an ultrasonic shear joint.

50(previously presented). A multi-component pharmaceutical dosage form according to claim 38 in which two adjacent sub-units are connected by a linker unit, in which at least one of the two adjacent sub-units is connected to the linker unit by a connection comprising interlocking tenons and an ultrasonic shear joint, one of said interlocking tenons being a collapsed form of a tenon which was initially longer than the other of said interlocking tenons.

51(previously presented). A multi-component pharmaceutical dosage form according to claim 38 in which the sub-units are held together in an assembled dosage form by one or more welds, at least one said weld being supplemented by a mechanical interconnection.

52(previously presented). A multi-component pharmaceutical dosage form according to claim 38 in which at least one of said sub-units is formed with a first interconnecting part, and an adjacent one of said sub-units is formed with a second interconnecting part which mates in interconnecting relationship with said first

interconnecting part.

53(cancelled).

54(previously presented). A multi-component pharmaceutical dosage form according to claim 38 in which at least one of said sub-units is a tub-shaped, drug substance-containing, capsule compartment which is soluble or disintegrable in a patient's gastro-intestinal environment, said tub-shaped capsule compartment having a base closed by a base wall, side walls extending from said base wall, and a mouth, and in which an adjacent one of said sub-units is formed with an element which mates in interconnecting relationship with said mouth and completes the enclosure of the drug substance within said tub-shaped capsule compartment.

55(previously presented). A multi-component pharmaceutical dosage form according to claim 38 in which at least one of said sub-units is a tub-shaped, drug substance-containing, capsule compartment which is soluble or disintegrable in a patient's gastro-intestinal environment, said tub-shaped capsule compartment having a base closed by a base wall, side walls extending from said base wall, and a mouth, and in which an adjacent one of said sub-units is formed with a plug which fits into said mouth and completes the enclosure of the drug substance within said tub-shaped capsule compartment.

56(previously presented). A multi-component pharmaceutical dosage form according to claim 38 in which at least one of said sub-units is a tub-shaped, drug substance-containing, capsule compartment which is soluble or disintegrable in a patient's gastro-intestinal environment, said tub-shaped capsule compartment having a base closed by a base wall, side walls extending from said base wall, and a mouth, and in which an adjacent one of said sub-units is formed with a cap which fits over said mouth and completes the enclosure of the drug substance within said tub-shaped capsule compartment.

57(previously presented). A multi-component pharmaceutical dosage form according to claim 38 in which at least one of said sub-units is a tub-shaped, drug substance-containing, capsule compartment which is soluble or disintegrable in a patient's gastro-intestinal environment, said tub-shaped capsule compartment having a base closed by a base wall, side walls extending from said base wall, and a mouth, in which an adjacent one of said sub-units is a solid matrix comprising a polymer and containing a drug substance, the polymer being soluble, dispersible or disintegrable in a patient's gastro-intestinal environment, and said solid matrix of said adjacent one of said sub-units is formed with an element which mates in interconnecting relationship with said mouth and completes the enclosure of the drug substance within said tub-shaped capsule compartment.

58(previously presented). A multi-component pharmaceutical dosage form according to claim 38 in which at least one of the sub-units is a drug substance-containing capsule compartment which is soluble or disintegrable in a patient's gastro-intestinal environment, and in which, said capsule compartment is welded to an adjacent one of said sub-units and closed by means independent of said adjacent one of said sub-units.

59(cancelled).

60(previously presented). A multi-component pharmaceutical dosage form according to claim 38 in which at least two adjacent sub-units are connected together by a linker unit, to which both of said adjacent sub-units are welded, the linker unit being in the form of a generally cylindrical body having a diameter to length ratio in the range of about 4:1 to 1.5:1 and having an end surface which is substantially planar over at least 50% of its area.

61(previously presented). A multi-component pharmaceutical dosage form according to claim 38 in which at least two adjacent sub-units are connected together by a linker unit, to which said adjacent sub-units are welded.

62(previously presented). A multi-component pharmaceutical dosage form according to claim 38 in which at least two adjacent sub-units are drug substance-containing capsule compartments having mouth openings facing each other, and having a linker unit with two oppositely facing plugs fitting into the mouth openings of the respective adjacent drug substance-containing capsule compartments and completing the enclosure of the drug substances in said adjacent drug substance-containing capsule compartments.

63(previously presented). A multi-component pharmaceutical dosage form according to claim 38 in which at least two adjacent sub-units are drug substance-containing capsule compartments having mouth openings facing each other, and having a linker unit with two oppositely facing plugs fitting into the mouth openings of the respective adjacent drug substance-containing capsule compartments and completing the enclosure of the drug substances in said adjacent drug substance-containing capsule compartments, the linker unit having two oppositely facing abutment surfaces, and the mouth opening of each of said adjacent sub-units having a rim engaged with one of said abutment surfaces.

64(previously presented). A multi-component pharmaceutical dosage form according to claim 38 in which at least two adjacent sub-units are drug substance-containing capsule compartments having mouth openings facing each other, and having a linker unit with two oppositely facing plugs fitting into the mouth openings of the respective adjacent drug substance-containing capsule compartments and completing the enclosure of the drug substances in said adjacent drug substance-containing capsule compartments, each plug being surrounded by an annular shoulder formed in the linker unit, and the mouth opening of each of said adjacent sub-units having a rim engaged with one of said shoulders.

65(previously presented). A multi-component pharmaceutical dosage form according to Claim 38 wherein the sub-units comprise at least two drug substance-

containing capsule compartments having differing wall thicknesses, whereby the thinner-walled compartment is disrupted more rapidly than the thicker-walled compartment.

66(previously presented). A multi-component pharmaceutical dosage form according to claim 38 wherein at least one of said sub-units is a drug substance-containing capsule compartment which is soluble or disintegrable in a patient's gastro-intestinal environment, a part of the last-mentioned compartment being weakened so that it dissolves preferentially.

67(currently amended). A set of multi-component dosage forms, each comprising a plurality of sub-units each sub-unit being selected from:

- (a) a drug substance-containing capsule compartment which is soluble or disintegrable in a patient's gastro-intestinal environment for release of the drug substance contained in the capsule compartment, and
- (b) a solid matrix comprising a polymer and containing a drug substance, the polymer being soluble, dispersible or disintegrable in a patient's gastro-intestinal environment for release of the drug substance contained in the solid matrix,

in which at least one of the dosage forms of the set comprises at least one said drug substance-containing capsule compartment and at least one other dosage form of the set comprises at least one said solid matrix, in which the drug substance-containing capsule compartment of said at least one of the dosage forms is interchangeable with said solid matrix of said at least one other dosage form, and in which at least prior to administration to a patient, the sub-units of each dosage form are welded together to provide an assembled dosage form, and wherein the drug substance in at least of the dosage forms of the set differs from the drug substance present in another of the sub-units of the set.

68(currently amended). A process for manufacturing a dosage form comprising a pair of drug substance-containing capsule compartments which are soluble or disintegrable in a patient's gastro-intestinal environment for release of the drug substance contained therein and a linker arranged between said capsule compartments for connecting the compartments together and having plug portions inserted into the capsule compartments and completing the enclosure of the drug substances therein, the process comprising the steps of

filling one of said capsule compartments with a first drug substance through an open end of said one of said capsule compartments;
inserting a first plug portion of a linker into said open end of said one of said capsule compartments;
welding the linker to said one of said capsule compartments;
filling the other of said capsule compartments with a second drug substance through an open end of said other of said capsule compartments;
inserting the other plug portion of the linker into said open end of said other of said capsule compartments; and
welding the linker to said other of said capsule compartments, and wherein the first drug substance is different from the second drug substance.

69(previously presented). A multi-component pharmaceutical dosage form according to Claim 38 wherein each of the sub-units of the multi-component pharmaceutical dosage form is joined to at least one other sub-unit by a joint comprising a plug constituting a unitary part of one of the joined units and a socket formed as a unitary part in the other of the joined sub-units, the plug and socket of each said joint each being radially smaller than the sub-unit of which it is a unitary part, and said plug closely fitting into said socket, said joined sub-units being secured together by a weld at the joint thereof.

70(cancelled).

71(previously presented). A multi-component pharmaceutical dosage form according to claim 63, wherein each said sub-unit is welded to the linker unit.

72(previously presented). A multi-component pharmaceutical dosage form according to claim 63, wherein each said sub-unit is welded, by an ultrasonic weld to the linker unit.